



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: Yat Sun Or, *et al*

EXAMINER: S. Liu

SERIAL NO.: 09/800,856

GROUP ART UNIT: 1653

FILED: March 5, 2001

ATTY. DOCKET NO.: ENP-019

TITLE: Cyclosporins for the Treatment of Respiratory Diseases

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RESPONSE TO REQUIREMENT FOR RESTRICTION AND
REQUIREMENT FOR ELECTION OF SPECIES

Box Non-Fee Amendment
Commissioner of Patents and Trademarks
Washington, D.C. 20231

Sir:

This paper is in response to the Office Action mailed October 1, 2002 in the above-identified application for Letters Patent.

1. The examiner has made a requirement for restriction between three groups of claims as follows:

I. Claims 1-4 and 8, drawn to a cyclosporin peptide and a process of making, are classified in class 530, subclass 317, class 514, subclass 2 and 11.

II. Claims 5-7, drawn to a method of making the cyclosporin and derivatives via an organic synthesis, are classified in class 530, subclass 333 and 335.

III. Claims 9-11, drawn to a method of treating inflammatory disease by administering a pharmaceutical composition comprising cyclosporin, are classified in class 514, subclass 2 and 11, class 424, subclass class 278.1, and class 604, subclass 19.

It should be noted that the examiner, apparently inadvertently, has referred to claim 8 as being drawn to a process of making when, in fact, it is directed to a pharmaceutical composition.

In support of the requirement for restriction the examiner has asserted that: a) the claims of Groups II and I are related as process of making and product made; b) the claims of Groups I and III are related as product and processes of use; and c) the claims of Group II and III are related as different and/or distinct methods, a method of making the cyclosporin and derivatives via synthesis, and method of treating inflammatory disease using a pharmaceutical composition comprising the cyclosporin.

Applicants request reconsideration of the requirement for restriction. The sets of claims, as grouped by the examiner, recite subject matter which is so closely related as to warrant examination of all the claims in the present application.

Restriction between claims of different statutory categories present in one application is not mandatory but rather is within the discretion of the United States Patent and Trademark Office ("USPTO"). The statutory authority for restriction practice, 35 USC §121, states that restriction between two or more independent and distinct inventions claimed in one application may (emphasis added) be required and further provides that the validity of a patent may not be questioned for failure to require the application to be restricted to one invention.

Here, all the claims in the application could be examined conveniently in this application since the compounds and compositions recited in the claims of Group I are recited in the Group II claims in the context of a method for making the compounds and in the Group III claims in the context of treating inflammatory disease by administering the pharmaceutical composition. Thus, the subject matter of the respective groups of claims is so closely related that the sound exercise of discretion dictates the examination of all the claims in the present application.

Nevertheless, should the USPTO continue to assert the requirement for restriction, applicants hereby provisionally elect the claims of Group I (1-4 and 8) for examination without prejudice to their right, pursuant to 35 USC §121, to file divisional applications directed to the non-elected claims.

2. The examiner has also required applicants to elect a single disclosed species for examination and to list all the claims readable thereon. Further, the

examiner has stated that if the claims of Group I are elected (as is the case here – see paragraph #1), applicant is required to elect a Y chemical group from claims 1-3 and a cyclosporin derivative from claim 4.

Applicants hereby elect, in compliance with the examiner's requirement, the compound of Formula I wherein B is $-\alpha\text{Abu}$, U is $-(\text{D})\text{Ala}$, X is absent and Y is $-\text{COOCH}_3$. This elected species is recited specifically in claim 4 and the Y group is recited in claims 1-3.

Claims 1-4 and 8 read on the elected species.

In summary, reconsideration of the restriction requirement, withdrawal thereof and examination of all the claims in the application are respectfully requested.

Respectfully submitted,

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I hereby certify that this correspondence is being deposited today with the United States Postal Service as First Class Mail in an envelope addressed to: Box Non-Fee Amendment, Commissioner for Patents, Washington, D.C. 20231.

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Date: 10/29/2002